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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,026	10/28/2003	Klaus Mosbach	003301-091	3683
21839 7590 12/14/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER EPPERSON, JON D	
			ART UNIT 1639	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/694,026	<b>Applicant(s)</b> MOSBACH ET AL.	
	<b>Examiner</b> Jon D. Epperson	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 23-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 and 23-35, drawn to method for producing molecularly imprinted microspheres, classified variously, for example, in class 216, subclass 56; class 265, subclass 330, 219.
  - II. Claims 36, drawn to a method for screening, classified variously, for example, in class 506, subclass 7.
  - III. Claims 37, drawn to method for conducting capillary electrophoresis, classified variously, for example, in class 204, subclass 164.
  - IV. Claims 38-40, drawn to a product described as the molecularly imprinted microspheres according to claim 1, classified variously, for example, in class 530, subclass 389.2 depending on the nature of the monomers used to make the microspheres.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I-III are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed, have a materially different design, mode of operation, function, or effect. For example, Group II results in the screening of

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a library whereas Group I results in the production of microspheres. Likewise, Group III results in a capillary electrophoreses/HPLC separation, not the production of microspheres.

Furthermore, Group II requires the use of a library, which is not required by the other Groups.

Likewise, Group III requires the use of a capillary electrophoresis or HPLC, which is not required by the other Groups. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (1) the process as claimed can be used to make a materially different product such as a molecularly imprinted film or gel. In addition, (2) the product as claimed can be made by another and materially different process such as dispersion or emulsion polymerization (e.g., see specification, page 2, last paragraph; see also page 5, paragraph 2).

5. Inventions II/III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, (2) the product as claimed can be used in a materially different process of using that product (e.g., Group II or III).

6. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either

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instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. In the event that the examiner has required restriction between product and process claims the following is noted:

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is

withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Additional Species Election***

8. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

**Group I**

9. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

**Subgroup 1: Species of molecularly imprinted microspheres produced (e.g., see claim 1)**

Applicant must elect, for the purposes of search, a **single species** of molecularly imprinted microspheres produced such as the anti-theophylline microspheres produced by the method of Example 1 or the anti-17 $\beta$ -estradiol microspheres produced by the method of Example 3.

**Subgroup 2: Species of functional monomers (e.g., see claim 1)**

Applicant must elect, for the purposes of search, a **single species** of functional monomers such as methacrylic acid shown in Example 1; see also figure 2 for list of other Examples. Please make sure to elect all functional monomers used to make the microspheres of subgroup 1 listed above if more than one monomer is employed. Applicants must further indicate whether said functional monomers have the same functionality or different functionality (e.g., see claims 26 and 27) and label said functionality.

**Subgroup 3: Species of cross-linkers (e.g., see claim 1)**

Applicant must elect, for the purposes of search, a **single species** of cross-linkers such as those set forth in Examples 1-3. Please make sure to elect all cross-linkers used to produce the microspheres produced in Subgroup 1 if more than one cross-linker is used.

**Subgroup 4: Species of solvent (e.g., see claim 1)**

Applicant must elect, for the purposes of search, a **single species** of solvent used such as acetonitrile (e.g., see example 1) or dichloromethane (e.g., see specification, page 6, line

25). Please make sure to elect all solvents used to produce the microspheres produced in Subgroup 1 if more than one solvent is used. Applicants must further indicate whether said solvent is aqueous or non-aqueous (e.g., see claim 24). Applicants must further indicate whether it is a single solvent or multi-solvent system (e.g., see claim 25).

Subgroup 5: Species of print molecules (e.g., see claim 1)

Applicant must elect, for the purposes of search, a single species of print molecules used such as theophylline or 17 $\beta$ -estradiol (e.g., see Examples 1 and 3).

Subgroup 6: Species of polymerization induction (e.g., see claim 29)

Applicant must elect, for the purposes of search, a single species of polymerization induction such as heat, UV,  $\gamma$ -radiation, etc. (e.g., see claim 29).

Subgroup 7: Species of polymerization process (e.g., see claim 30)

Applicant must elect, for the purposes of search, a single species of polymerization process such as free-radical, ionic, coordination polymerization, etc.

Subgroup 8: Species of size control (e.g., see claims 31 and 32)

Applicant must elect, for the purposes of search, a single species of size control including nucleation/particle growth process. Applicants must further indicate whether functional monomer/crosslinker/solvent and/or reaction conditions during polymerization were adjusted to control said growth. Applicants must also indicate whether it was intended to avoid aggregation of the microspheres (e.g., see claim 33). Applicants must also indicate whether the particles produced are monodispers (e.g., see claim 35).

Group II

10. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 36 is generic.

Subgroup 1: Species of molecularly imprinted microspheres (e.g., see claim 36)

Applicant must elect, for the purposes of search, a single species of molecularly imprinted microspheres produced such as the anti-theophylline microspheres produced by the method of Example 1 or the anti-17 $\beta$ -estradiol microspheres produced by the method of Example 3.



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Subgroup 2: Species of screening (e.g., see claim 36)

Applicant must elect, for the purposes of search, a single species of screening such as for catalysis, facilitating synthesis, analyte determination using ligand binding assays, agglutinations assays, etc. (e.g., see claim 36).

Group III

11. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 37 is generic.

Subgroup 1: Species of molecularly imprinted microspheres (e.g., see claim 37)

Applicant must elect, for the purposes of search, a single species of molecularly imprinted microspheres produced such as the anti-theophylline microspheres produced by the method of Example 1 or the anti-17 $\beta$ -estradiol microspheres produced by the method of Example 3.

Subgroup 2: Species of separation method (e.g., see claim)

Applicant must elect, for the purposes of search, a single species of separation method such as CE, HPLC, etc. (e.g., see claim 37)

Group IV

12. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct specie. Claim 38 is generic.

Subgroup 1: Species of molecularly imprinted microspheres (e.g., see claim 38)

Applicant must elect, for the purposes of search, a single species of molecularly imprinted microspheres produced such as the anti-theophylline microspheres produced by the method of Example 1 or the anti-17 $\beta$ -estradiol microspheres produced by the method of Example 3.

13. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not

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obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Jon D. Epperson/

Primary Examiner, AU 1639